MAR - 4 2004

510(k) Summary
for Mission Diagnostic Reagents
on pH/Blood Gas &/or Electrolyte Analyzers

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: 3003656721

Date of Preparation: Dec. 29, 2003

2. **Identification of the Device:**

Proprietary/Trade name:	Calibrating Material, Calibrating standards
Common or usual name	Calibrators for ISE and/or pH/Blood Gas automated systems
Classification name:	Calibrator, secondary
Device Classification	II
Regulation Number:	21 CFR § 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

- Mission manufactures calibrators intended to serve as direct replacements to like named products manufactured by Original Equipment Manufactures (OEM)

3. **Predicate Device:**

- Mission claims substantial equivalence to the OEM Calibrating Materials listed below:

Substantial Equivalence Table of Product PN's & Trade Names – Mission vs OEM

	Mission Diagnostics		OEM* Equivalent			
#			Predicate Device			Cleared Date
1	AV-BP1579D	BG Calibrator	BP1579	BG Calibrator	K943570	08-24-1994
2	CD-105670D	Hct Slope	105670	Hct Slope	K962021	06-24-1996
3	CD-471818D	634 Ca/pH Slope Standard	471818	634 Slope Standard $2.50^{Ca}/6.84^{pH}$	K844188	11-23-1988
4	CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	473606	654 Lithium Slope Solution 2.50 mmol/L	K884769	01-17-1989
5	CD-473692D	pH Blood Gas Slope	473692	pH Blood Gas Slope	K904188	09-27-1990
6	RD-944015D	Calibrating Solution 1, Bt # 9	944015	Calibrating Solution 1, Btl# 9	K954612	11-09-1995
7	RD-944030D	Calibrating Solution 1, Bt # 3	944030	Calibrating Solution 1, Btl# 3	K973367	10-06-1997
8	RD-944031D	Calibrating Solution 2, Bt # 4	944031	Calibrating Solution 2, Btl# 4		
9	BK-465908D	Calibrator 1	465908	Calibrator 1	K942676	11-02-1994
10	BK-465909D	Calibrator 2	465909	Calibrator 2		
11	BK-465910D	Calibrator 3	465910	Calibrator 3		
12	BK-443360D	Calibration Standard 1	443360	Calibration Standard 1	K864236	12-31-1986
13	BK-443365D	Calibration Standard 2	443365	Calibration Standard 2		
14	BM-620427D	ISE Standard High	620427	ISE Standard High	K811194	05-27-1981
15	BM-620428D	ISE Standard Low	624028	ISE Standard Low		

* OEM = Original Equipment Manufacturer

4. Device Description:

- The Calibrators for the OEM Instruments are aqueous reagents with salts (chemical constituents) added to obtain desired analyte levels to provide the desired calibration.

- **Intended Use:**

- For each Calibrator included in this submission, the calibrator is intended for use on equivalent OEM Instruments, i.e. predicate device and are necessary for the continued operation and use of the instruments.

PN	Description	Intended Use
AV-BP1579D	BG Calibrator	Provide a second calibration point for AVL Compact 1 pH/Blood Gas Analyzer.
CD-105670D	Hct Slope	Provide a second calibration point for the Hct sensor on the 348 Analyzer.
CD-471818D	634 Ca/pH Slope Standard	To provide a second calibration point for the Ca & pH electrodes on the 634 Ca/pH Analyzer.
CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	To provide a second calibration point for the Lithium electrode on the 654 Na/K/Li Analyzer.
CD-473692D	pH Blood Gas Slope	To provide a second calibration point for pH, pCO_2, and pO_2 on 238 pH/Blood Gas Analyzer.
RD-944015D	Calibrating Solution 1, Btl# 9	To provide a calibration point for the Na^+, K^+, Ca^{++}, Cl^-, pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944030D	Calibrating Solution 1, Btl# 3	To provide a calibration point for the Na^+, K^+, Ca^{++}, Cl^-, pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944031D	Calibrating Solution 2, Btl# 4	To provide a second calibration point for the Na^+, K^+, Ca^{++}, Cl^-, and pH electrodes on Radiometer 555 Analyzer.
BK-465908D	Calibrator 1	Used in conjunction with Calibrator 2 and 3 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465909D	Calibrator 2	Used in conjunction with Calibrator 1 and 3 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465910D	Calibrator 3	Used in conjunction with Calibrator 1 and 2 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-443360D	Calibration Standard 1	Used in conjunction with Calibration Standard 2 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BK-443365D	Calibration Standard 2	Used in conjunction with Calibration Standard 1 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BM-620427D	ISE Standard High	To provide a calibration point for Na+, K+ and Cl- electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.
BM-620428D	ISE Standard Low	To provide a calibration point for Na+, K+ and Cl- electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.

- For each Calibrator included in this submission, Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

5. Performance Characteristics:

See table below for Summary.

<table>
<tr><th>PN</th><th>Description</th><th>Performance Data collected:</th><th>Results:</th></tr>
<tr><td>CD-105670D</td><td>Hct Slope</td><td>Precision and correlation data are collected per:
SOP23-01-02 Performance Study Protocol for 510(k) Submission with the following modifications:
Testing was conducted over 7 days, 2 runs each, Mission and OEM, per day.
The 348 Hct sensor was sloped with the OEM Hct slope and Hct QC samples were measured in duplicate. The Hct Sensor was calibrated and Hct QC samples were measured in duplicate – this equaled 1 run, n= 4 per QC sample. 2 runs were completed each day, n=8 per QC sample.
The 348 Hct sensor was sloped with the Mission Hct slope and Hct QC samples were measured in duplicate. The Hct Sensor was calibrated and Hct QC samples were measured in duplicate – this equaled 1 run, n= 4 per QC sample. 2 runs were completed each day, n=8 per QC sample.
Hct Slope is an ampuled product used to provide a slope point for the Hct sensor. Other required reagents to run the 348 instrument remained constant throughout testing.</td><td>Summary of QC Recovery and Precision for 348 Hct Slope CD-105670D
Summary of QC Data
<table>
<tr><th>Analyte</th><th>Level</th><th>N</th><th>Mean</th><th>Sd</th><th>Min</th><th>Max</th><th>%CV</th></tr>
<tr><td>%Hct</td><td>QC – A</td><td>56</td><td>26</td><td>0.6</td><td>24</td><td>27</td><td>2.2</td></tr>
<tr><td></td><td>QC – B</td><td>56</td><td>48</td><td>0.8</td><td>45</td><td>49</td><td>1.6</td></tr>
<tr><td>OEM</td><td colspan="7"></td></tr>
<tr><td>%Hct</td><td>QC – A</td><td>48</td><td>27</td><td>0.3</td><td>26</td><td>27</td><td>1.0</td></tr>
<tr><td></td><td>QC – B</td><td>48</td><td>49</td><td>0.6</td><td>48</td><td>50</td><td>1.2</td></tr>
</table>
Recoveries of individual QC observations when 348 Hct sensor sloped with Mission Hct Slope vs OEM Hct Slope were compared by least squares regression. The following statistics were obtained:

Mission = 0.999 x Corning – 0.818
Range = 26 & 48 %Hct; r^2 = 0.997; df = 95; n = 96; $S_{(y.x)}$ = 0.58 %Hct

Mission Hct Slope performed equally to the OEM Hct Slope.</td></tr>
</table>

PN	Description	Performance Data collected:	Results:

CD-471818D	634 Ca/pH Slope Standard	Precision and correlation data are collected per:
		• SOP23-01-02 Performance Study Protocol for 510(k) Submission with the following modifications:
		  • Serum_samples were spiked or diluted to yield Ca samples ranging from 0.37-4.57 mmol/L. 5 replicates of a serum sample and 1 replicate of each of 3 levels of QC were tested in a calibrated run. Samples were tested over a three-day period.
		  • All samples and QC's were tested in calibrated runs where Mission 634 Ca/pH Slope was used for the slope point and in calibrated runs where the OEM 634 Slope Standard was used for the slope point.
		The 634 Ca/pH Slope Standard is an ampuled product used to provide a slope point for Ca & pH on the 634. Other required reagents to run the 634 instrument remained constant throughout testing.
			Table of QC Data for 634 Ca/pH Slope CD-471818D & OEM
			Summary QC Data for Ca and pH – with Mission 634 Slope
			
			Analyte / Level / N / Mean / Sd / Min / Max / %CV
			pH / 1 / 12 / 7.11 / 0.04 / 7.05 / 7.18 / 0.62
			pH / 2 / 12 / 7.41 / 0.02 / 7.37 / 7.45 / 0.33
			pH / 3 / 12 / 7.60 / 0.01 / 7.58 / 7.62 / 0.18
			Ca / 1 / 12 / 2.13 / 0.03 / 2.08 / 2.15 / 1.32
			Ca / 2 / 12 / 1.07 / 0.01 / 1.06 / 1.08 / 0.62
			Ca / 3 / 12 / 0.56 / 0.01 / 0.55 / 0.56 / 1.50
			
			Summary QC Data for Ca and pH – with Corning 634 Slope
			
			Analyte / Level / N / Mean / Sd / Min / Max / %CV
			pH / 1 / 12 / 7.18 / 0.05 / 7.08 / 7.22 / 0.67
			pH / 2 / 12 / 7.41 / 0.04 / 7.36 / 7.50 / 0.54
			pH / 3 / 12 / 7.58 / 0.02 / 7.57 / 7.63 / 0.21
			Ca / 1 / 12 / 2.10 / 0.03 / 2.08 / 2.15 / 1.24
			Ca / 2 / 12 / 1.08 / 0.01 / 1.06 / 1.09 / 0.84
			Ca / 3 / 12 / 0.57 / 0.01 / 0.55 / 0.59 / 1.90
			
			Recoveries of individual serum observations were compared by least squares regression. The following statistics were obtained:
			
			Mission = 1.018 x Corning – 0.019
			Range = 0.37 to 4.57 mmol/L; r^2 = 0.998; df = 68; n = 69; $S_{(y.x)}$ = 0.05 mmol/L
			
			Recoveries of individual QC observations when 634 calibrated with Mission 634 Ca/pH Slope Standard vs OEM 634 Slope Standard were compared by least squares regression. The following statistics were obtained:
			For Ca
			Mission = 1.028 x Corning – 0.031
			Range = 0.55 – 2.18; r^2 = 0.998; df = 32 n = 33; $S_{(y.x)}$ = 0.02 mmol/L Ca
			
			For pH
			Mission = 1.045 x Corning – 0.36
			Range = 7.05 – 7.62; r^2 = 0.937; df = 32; n = 33; $S_{(y.x)}$ = 0.05
			
			Mission 634 Ca/pH Slope performed equally to the OEM 634 Slope Standard.

PN	Description	Performance Data collected:	Results:

CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	Precision and correlation data are collected per:
		• SOP23-01-02 Performance Study Protocol for 510(k) Submission with the followingmodifications:
		  • Serum_samples were spiked or diluted to yield Li samples ranging from 0.28 – 2.95 mmol/L. 5 replicates of a serum sample and 1 replicate of each of 3 levels of QC were tested in a calibrated run. Samples were tested over a four-day period.
		  • All samples and QC's were tested in calibrated runs where Mission 654 Li Slope was used for the slope point and in calibrated runs where the OEM 654 Li Slope Standard was used for the slope point.
		The 654 Li Slope Standard is an ampuled product used to provide a slope point for Li on the 654. Other required reagents to run the 654 instrument remained constant throughout testing.
			Table of QC Data for 654 Li Slope CD-473606D & OEM
			Summary of QC Data with Mission 654 Li Slope Standard

Analyte	Level	N	Mean	Sd	Min	Max	%CV
Na	1	20	119	0.6	118	120	0.5
	2	20	141	0.6	140	142	0.4
	3	20	165	0.7	164	167	0.4
K	1	20	2.09	0.03	2.00	2.14	1.59
	2	20	4.26	0.05	4.10	4.34	1.09
	3	20	6.71	0.09	6.40	6.83	1.36
Li	1	20	0.33	0.02	0.29	0.38	6.8
	2	20	1.14	0.05	1.06	1.22	4.3
	3	20	2.17	0.09	2.01	2.28	4.0

Summary of QC Data with OEM 654 Li Slope Standard

Analyte	Level	N	Mean	Sd	Min	Max	%CV
Na	1	20	119	0.6	118	120	0.5
	2	20	141	0.6	140	142	0.4
	3	20	166	0.5	165	166	0.3
K	1	20	2.10	0.02	2.05	2.13	1.04
	2	20	4.26	0.03	4.20	4.32	0.76
	3	20	6.72	0.08	6.59	6.90	1.17
Li	1	20	0.38	0.02	0.34	0.42	5.2
	2	20	1.14	0.04	1.09	1.19	3.1
	3	20	2.10	0.06	2.02	2.18	2.7

Recoveries of individual serum observations were compared by least squares regression. Scatter plot of individual observations are below. The following statistics were obtained:

Mission = 1.050 x Corning – 0.075
Range = 0.28 to 2.95 mmol/L; $r^2 = 0.998$; df = 27; n = 28; $S_{(y.x)} = 0.04$ mmol/L Li

Mission 654 Li Slope Standard performed equally to the OEM 654 Li Slope Standard.

PN	Description	Performance Data collected:	Results:

CD-473692D	pH Blood Gas Slope	Precision and correlation data are collected per:
		• SOP23-01-02 Performance Study Protocol for 510(k) Submission with the following modifications:
		  • Testing was conducted over 5 days, 2 runs each, Mission and OEM, per day.
		  • The 238 was calibrated then sloped with Mission pH/Blood Gas Slope. 3 levels of QC were tested: QC 1, QC2, QC3, QC3, QC2, QC1 – a new ampule tested for each sample. The 238 was calibrated and 3 levels of QC tested as before. This equaled 1 run, n= 4 for each QC level. 2 runs were completed each day, n=8 per QC sample.
		  • The 238 was calibrated and then sloped with the OEM pH/Blood Gas Slope. 3 levels of QC were tested: QC 1, QC2, QC3, QC3, QC2, QC1 – a new ampule tested for each sample. The 238 was calibrated and 3 levels of QC tested as before. This equaled 1 run, n= 4 for each QC level. 2 runs were completed each day, n=8 per QC sample.
		The pH/Blood Gas Slope is an ampuled product used to provide a slope point for pH, pCO_2, pO_2 on the 238. Other required reagents to run the 238 instrument remained constant throughout testing.
			Table of QC Data for 238 Slope CD-473692D vs OEM
			Summary of QC Data – with Mission 238 Slope
			
			Analyte / Level / N / Mean / Sd / Min / Max / %CV
			pH / 1 / 36 / 7.05 / 0.01 / 7.02 / 7.08 / 0.02
			2 / 38 / 7.33 / 0.02 / 7.30 / 7.38 / 0.25
			3 / 40 / 7.55 / 0.02 / 7.50 / 7.60 / 0.30
			pCO_2 / 1 / 36 / 95 / 2.1 / 92 / 99 / 2.2
			2 / 38 / 47 / 1.5 / 44 / 50 / 2.1
			3 / 40 / 22 / 0.6 / 21 / 23 / 2.6
			pO_2 / 1 / 36 / 73 / 1.2 / 71 / 76 / 1.6
			2 / 38 / 113 / 4.1 / 106 / 121 / 3.7
			3 / 40 / 133 / 3.6 / 128 / 142 / 2.7
			
			Summary of QC Data – with OEM 238 Slope
			
			Analyte / Level / N / Mean / Sd / Min / Max / %CV
			pH / 1 / 37 / 7.06 / 0.02 / 7.02 / 7.11 / 0.24
			2 / 40 / 7.33 / 0.02 / 7.29 / 7.36 / 0.23
			3 / 39 / 7.54 / 0.02 / 7.49 / 7.57 / 0.26
			pCO_2 / 1 / 37 / 90 / 2.1 / 87 / 94 / 2.4
			2 / 40 / 46 / 1.3 / 44 / 49 / 2.8
			3 / 39 / 22 / 0.7 / 21 / 23 / 3.0
			pO_2 / 1 / 37 / 73 / 1.3 / 70 / 75 / 1.8
			2 / 40 / 113 / 4.3 / 103 / 122 / 3.8
			3 / 39 / 132 / 3.6 / 132 / 143 / 2.8
			
			Recoveries for **pH** of individual QC observations were compared by least squares regression. The following statistics were obtained:
			
			Mission = 1.053 x Corning – 0.392
			Range = 7.02 to 7.60; $r^2 = 0.987$; df = 112; n = 113; $S_{(y.x)} = 0.02$
			
			Recoveries for **pH** of individual QC observations were compared by least squares regression. The following statistics were obtained:
			
			Mission = 1.053 x Corning – 0.392
			Range = 7.02 to 7.60; $r^2 = 0.987$; df = 112; n = 113; $S_{(y.x)} = 0.02$
			
			Recoveries for **pO_2** of individual QC observations were compared by least squares regression. The following statistics were obtained:
			
			Mission = 1.001 x Corning + 0.661
			Range = 71 to 142 mm Hg pO_2; $r^2 = 0.972$; df = 112; n = 113; $S_{(y.x)} = 4.19$ mm Hg
			
			Mission 238 pH/Blood Gas Slope performed equally to the OEM 238 pH/Blood Gas Slope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 4 2004

Diamond Diagnostics, Inc.
c/o Ms. Linda M. Stundtner
QA/RA Manager
Mission Diagnostics Division
331 Fiske Street
Holliston, MA 01746

Re: k033060
Trade/Device Name: Mission Diagnostic Reagents for pH/BG &/or Electrolyte Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: December 29, 2003
Received: January 20, 2004

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k(Number K033060

Device Name: Mission Diagnostic Reagents for pH/BG &/or Electrolyte Analyzers

Indication For Use:

- The products encompassed by this request are intended for in-vitro diagnostics use and are intended for use in calibrating equivalent OEM Analyzers.

PN	Description	Intended Use
AV-BP1579D	BG Calibrator	Provide a second calibration point for AVL Compact 1 pH/Blood Gas Analyzer.
CD-105670D	Hct Slope	Provide a second calibration point for the Hct sensor on the 348 Analyzer.
CD-471818D	634 Ca/pH Slope Standard	To provide a second calibration point for the Ca & pH electrodes on the 634 Ca/pH Analyzer.
CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	To provide a second calibration point for the Lithium electrode on the 654 Na/K/Li Analyzer.
CD-473692D	pH Blood Gas Slope	To provide a second calibration point for pH, pCO_2, and pO_2 on 238 pH/Blood Gas Analyzer.
RD-944015D	Calibrating Solution 1, Btl# 9	To provide a calibration point for the Na^+, K^+, Ca^{++}, Cl^-, pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944030D	Calibrating Solution 1, Btl# 3	To provide a calibration point for the Na^+, K^+, Ca^{++}, Cl^-, pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944031D	Calibrating Solution 2, Btl# 4	To provide a second calibration point for the Na^+, K^+, Ca^{++}, Cl^-, and pH electrodes on Radiometer 555 Analyzer.
BK-465908D	Calibrator 1	Used in conjunction with Calibrator 2 and 3 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465909D	Calibrator 2	Used in conjunction with Calibrator 1 and 3 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465910D	Calibrator 3	Used in conjunction with Calibrator 1 and 2 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-443360D	Calibration Standard 1	Used in conjunction with Calibration Standard 2 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BK-443365D	Calibration Standard 2	Used in conjunction with Calibration Standard 1 to calibrate Na, K, Cl, Ca, TCO_2, Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BM-620427D	ISE Standard High	To provide a calibration point for Na+, K+ and Cl- electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.
BM-620428D	ISE Standard Low	To provide a calibration point for Na+, K+ and Cl- electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.

- Mission reagents are intended to serve as direct replacements to the predicate device manufactured by the OEM.
- The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of the Device Evaluation (ODE)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional format 3-10-98)

X Prescription Use

510(k) K033060